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Dated: September 26, 2007 Signature: Donna V. Merryman
Donna V. Merryman

Docket No.: 63573(50533)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
John S. Haurum

Application No.: 10/540,227

Confirmation No.: 6313

Filed: March 6, 2006

Art Unit: 1639

For: METHOD FOR MANUFACTURING RECOMBINANT POLYCLONAL PROTEINS

Examiner: Teresa D. Wessendorf

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1-40 and 48-52 are pending in the application and are subject to restriction. The Office Action, on page 2, requires restriction to one of the following groups under 35 U.S.C. §121:

Group I: Claims 1-3, 5-14, 17-20 drawn to a method for generating a collection of cells encoding antibody;

Group II: Claims 1, 4, 13 and 15-16, drawn to a method for generating a collection of cells encoding polyclonal T receptor;

Group III: Claims 21-27 and 29-31, drawn to a method for the manufacture of a polyclonal protein;

Group IV: Claims 21 and 28, drawn to a method for the manufacture of a polyclonal protein wherein the polyclonal protein is a T cell receptor or fragment thereof;

Group V: Claims 32-33, 35-38, 40, 48-50 and 52, drawn to a recombinant polyclonal comprising a collection of cells;

Group VI: Claims 32, 34, 37, 39-40, 48-50 and 52, drawn to a recombinant polyclonal cell line with the library encoding T cell receptor;

Group VII: Claim 51, drawn to a polyclonal antibody;

In the event Applicants elected Group I-IV, the Examiner has required election of a further species from Group 1 and Group 2.

Species group 1. Screening procedure as recited in claim 10.

Species group 2. Mammalian cell line as recited in claim 20.

For Group V, the Examiner has required election of a further species from the Species Group 1.

In response to the restriction requirement, Applicant hereby provisionally elects the invention of Group V, claims 32, 33, 35-38, 40, 48-50, and 52, and in response to the requirement that Applicant elects a single species for prosecution, Applicant provisionally elects a mammalian cell line. Applicant respectfully traverses the requirements for restriction and election, and submits that the requirements are improper.

Applicant notes that contrary to the Office's assertion in the Restriction Requirement mailed on July 26, 2007, Groups V, VI, and VII are uniformly drawn to a recombinant polyclonal manufacturing **cell line** or **cell collection**, each cell of which encodes a distinct member of a polyclonal protein that binds an antigen. More particularly, with respect to Group V, contrary to the Office's assertion at page 3, second paragraph, the invention is **not** directed to a nucleic acid encoding a recombinant protein, but is directed to a **cell line** expressing a polyclonal protein. Similarly, with respect to Group VII, contrary to the Office's assertion at page 3, second paragraph, claim 51 is **not** directed to an antibody, but is directed to a **cell line** expressing a polyclonal antibody protein. Given that each of the claims of Groups V, VI, and VII is directed to cells that express polyclonal proteins, Applicants believe that the Restriction Requirement was based on a misreading of the claims. Accordingly, rejoinder of the invention of Groups V, VI, and VII, which are all directed to a single product (i.e., a cell line or cell collection where each of the cells expresses a distinct member of a polyclonal protein that binds an antigen) is proper, and is respectfully requested.

Under 37 CFR 1.475:

> An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories . . . A product, a process specially adapted for the manufacture of the said product, and a use of the said product.

Accordingly, under the PCT guidelines, restriction between a product, a process for making the product, and a use of the product is improper.

As detailed above, the invention of Group V is **a product**. The claims of Group I and Group II are directed to **methods for making the product** of Group V (i.e., the claimed cell lines and cell collections). Similarly, the claims of Groups III and IV are directed to **methods of using the product**. Specifically, the claims of Group III and IV are directed to methods of using the cell lines of Groups V-VII to manufacture polyclonal proteins. Clearly, the Office is requiring restriction between a product, and process for making the product, and a use of the product. Under 37 CFR 1.475, this restriction requirement is improper, and for this reason alone, the restriction requirement is improper and should be withdrawn.

In addition, Applicants assert that the subject matter of these groups represent different embodiments of a single inventive concept for which a single patent should issue. The pending claims represent an intricate web of knowledge, continuity of effort, and consequences of a single invention, which merit examination of all of these claims in a single application. More particularly, special technical features under Rule 13.2 PCT link all of the claims. This single, searchable, unifying aspect comprises the discovery that a collection of cells may be used to express polyclonal proteins, each of which binds a particular antigen. Moreover, each distinct member of these polyclonal proteins is expressed using an expression construct that has been integrated into the genome of each cell at a specific integration site.

In addition, Applicants submit that a sufficient search and examination with respect to the subject matter of all claims can be made without serious burden. As the M.P.E.P. states:

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. M.P.E.P. § 803 (8th ed., Rev. No. 2, May 2004).

That is, even if the above-enumerated groups of claims are drawn to distinct inventions, the Examiner must still examine the entire application on the merits because doing so will not result in a serious burden. This is especially true given the robust and extensive computerized search

engines and databases at the Examiner's disposal. Moreover, Applicants note that the entire application was searched by the international Examiner, and that the International Search Report was provided to the U.S. Patent and Trademark Office at the time of filing. Accordingly, it is respectfully requested that the restriction requirement be reconsidered and the elected claims of Group V be rejoined with those of Group I-IV and VI-VII.

Should the Examiner maintain her species election requirements, Applicants fully intend to seek rejoinder of any non elected species that require all the limitations of an allowable claim.

Applicants have contacted the Examiner to schedule an interview prior to the issuance of a First Office action. Applicants feel that a discussion of the Restriction Requirement may be useful in clarifying the grounds for traversal, and will be helpful in addressing any questions the Examiner may have regarding the claimed invention.

Applicants believe no additional fee is due with this response. However, if any additional fee is due, please charge our Deposit Account No. . 04-1105.

Dated: September 26, 2007
Customer No.: 21874

Respectfully submitted,

By _____
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